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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/536,939	04/11/2006	Christophe Revirron	05-403	8331

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EXAMINER	
RAMACHANDRAN, UMAMAHESWARI	
ART UNIT	PAPER NUMBER
1617	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	01/17/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	10/536,939	REVIRRON, CHRISTOPHE	
	Examiner	Art Unit	
	Umamaheswari Ramachandran	1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *27 May 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *10-21* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *10-21* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claims 10-21 are pending.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 10-21 are rejected under 35 U.S.C. 112, first paragraph, while enabling for the treatment of persistent allergic rhinitis the specification does not reasonably provide enablement for inhibiting, which is stopping or preventing the persistent allergic rhinitis. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to the invention commensurate in scope with these claims.

The instant specification fails to provide information that would allow the skilled artisan to practice the instant invention without undue experimentation. Attention is directed to In re Wands, 8 USPQ2d 1400 (CAFC 1988) at 1404 where the court set forth the eight factors to consider when assessing if a disclosure would have required undue experimentation. Citing Ex parte Forman, 230 USPQ 546 (BdApls 1986) at 547 the court recited eight factors:

(1) the nature of the invention; (2) the state of the prior art; (3) the relative skill of those in the art; (4) the predictability or unpredictability of the art; (5) the breadth of the claims; (6) the amount of direction or guidance presented; (7) the presence or absence of working examples; and (8) the quantity of experimentation necessary.

(1) The nature of the Invention:

The rejected claims are drawn to a method of treating or inhibiting persistent allergic rhinitis comprising administering an effective amount of Levocetirizine.

(2) Breadth of the claims:

Claim 1 is broad as it is drawn to a method of treating or inhibiting persistent allergic rhinitis comprising administering an effective amount of Levocetirizine. The complex nature of the subject matter of this invention is greatly exacerbated by the breadth of the claim.

(3) Guidance of the Specification:

The guidance given by the specification for inhibiting (stopping or preventing) persistent allergic rhinitis comprising administering an effective amount of Levocetirizine is lacking. No examples are provided for inhibiting persistent allergic rhinitis comprising administering an effective amount of Levocetirizine.

(4) Working Examples:

The specification provides examples for the treatment of persistent allergic rhinitis comprising administering an effective amount of Levocetirizine and no examples are provided for inhibiting persistent allergic rhinitis.

(5) The relative skill of those in the art:

The relative skill of those in the medical treatment art is high, requiring advanced education and training.

(6) The predictability of art:

Claims 10-15 are directed to the method of treatment or inhibition of persistent allergic rhinitis comprising administering an effective amount of Levocetirizine. The claims are so broad and there is a high degree of unpredictability involved. Despite the advanced training in the medical treatment arts, the arts are highly unpredictable.

(7) The Quantity of Experimentation Necessary:

In order to practice the above claimed invention, one of skill in the art would have to first envision formulation, dosage, duration, route and, in the case of human treatment, an appropriate animal model system to test Levocetirizine, to determine whether or not they are useful in inhibiting persistent allergic rhinitis. If unsuccessful, which is likely given the lack of significant guidance from the specification regarding the method of inhibition of persistent allergic rhinitis comprising administering an effective amount of Levocetirizine, one of skill in the art would have to envision a modification in the formulation, dosage, duration, route of administration etc. and appropriate animal model system, or envision an entirely new combination of the above and test the system again. Therefore, it would require undue, unpredictable experimentation to practice the claimed invention of inhibiting persistent allergic rhinitis by administering Levocetirizine. Applicant fails to provide information sufficient to practice the claimed invention, absent undue experimentation. Genetech, 108 F.3d at 1366 states that "a patent is not a hunting license. It is not a reward for search, but compensation for its successful conclusion" and "patent protection is granted in return for an enabling disclosure of an invention, not for vague intimations of general ideas that may or may not be workable".

Claim Rejections - 35 USC § 102

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claim 10 is rejected under 35 U.S.C. 102(b) as being anticipated by Gensthaler (Pharmazeutische Zeitung, vol. 146, no. 7, 2001-02-15, p 35-36, XP001147797).

Gensthaler teaches that Levocetirizine was effective in the treatment of patients with seasonal allergic rhinitis (p 35, para 4 lines 1-2). The reference further teaches an intended study of the long-term effect of Levocetirizine in 500 adults with persistent allergic rhinitis (p 36, lines 3-8).

Claims 11-12, 14-15, 17, 18, 20-21 are rejected under 35 U.S.C. 102(b) as being anticipated by Gray (WO 94/06429).

Gray teaches a method of treating the symptoms of seasonal and perennial allergic rhinitis such as sneezing, rhinorrhea, nasal congestion and pruritus in human comprising administering Levocetirizine in a dosage of about 1 mg to about 25 mg (p 12, lines 2-6, claims 1, 4).

Claims 11-15, 17-21 are rejected under 35 U.S.C. 102(b) as being anticipated by Leynadier et al. (Acta Otorhinolaryngol Belg. 2001, 55(4):305-12).

Leynadier et al. teaches a method of treatment for the seasonal allergic rhinitis with the symptoms sneezing, rhinorrhea, nasal congestion nasal pruritus, ocular pruritis, itchy eyes and itchy nose comprising administering 5mg of Levocetirizine (see Abstract).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 10 and 16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gensthaler (Pharmazeutische Zeitung, vol. 146, no. 7, 2001-02-15, p 35-36) in view of Leynadier et al (Acta Otorhinolaryngol Belg. 2001, 55(4):305-12).

Gensthaler's teachings are discussed above.

The reference does not explicitly teach a dosage in the intended study of persistent allergic rhinitis.

Leynadier et al teaches a dosage of 2.5, 5, 10 mg/day of levocetirizine in a method of treatment for seasonal allergic rhinitis with symptoms such as sneezing, rhinorrhea, nasal congestion, nasal pruritus, ocular pruritis, itchy nose and itchy eyes. For example, administration of 2.5, 5 and 10 mg of Levocetirizine to a patient would amount to 0.035 mg/kg, 0.07 mg/kg, and 0.14 of body weight, which falls within the range claimed in claim 16.

It would have been obvious to one of ordinary skill in the art at the time of the claimed invention to administer a dose of 0.0005 mg to about 2 mg per kg of body weight per patient for the treatment of persistent allergic rhinitis. The motivation to do so is provided by Leynadier et al. The reference teaches that Levocetirizine was significantly superior to placebo in reducing the symptom severity with an important

global treatment effect. The reference further teaches that a dosage of 5 mg of Levocetirizine once daily has an optimal benefit/ratio in the treatment of seasonal allergic rhinitis. Hence it would have been obvious to one of ordinary skill in the art at the time of the claimed invention to use a dosage of Levocetirizine as in claim 16 for the treatment of persistent allergic rhinitis as the symptoms rhinrrhea, nasal obstruction, nasal itching, sneezing, ocular pruritis are the same for seasonal allergic rhinitis.

Conclusion

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Umamaheswari Ramachandran whose telephone number is 571-272-9926. The examiner can normally be reached on M-F 8:30 AM - 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan can be reached on 571-272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

SREENI PADMANABHAN
SUPERVISORY PATENT EXAMINER